(vi) The date of manufacture and appropriate storage instructions adequate to protect the stability of the product. When applicable, these instructions shall include such information as conditions of temperature, light, humidity, date of expiration, and other pertinent factors. The basis for such instructions shall be determined by reliable, meaningful, and specific test methods, such as those described in § 211.166 of this chapter;

(vii) A declaration of the net quantity of contents, expressed in terms of weight or volume, numerical count, or any combination of these or other terms that accurately reflect the contents of the package. The use of metric designations is encouraged, wherever appropriate;

(viii) The name and place of business of manufacturer, packer, or distributor;

(ix) A lot or control number, identified as such, from which it is possible to determine the complete manufacturing history of the product;

(x) For class I exempt ASR's, the statement: ''Analyte Specific Reagent. Analytical and performance characteristics are not established''; and

(xi) For class II and III ASR's, the statement: ''Analyte Specific Reagent. Except as a component of the approved/cleared test (Name of approved/cleared test), analytical and performance characteristics of this ASR are not established.''

(2) In the case of immediate containers too small or otherwise unable to accommodate a label with sufficient space to bear all such information, and which are packaged within an outer container from which they are removed for use, the information required by paragraphs (e)(1) through (e)(6) of this section may appear in the outer container labeling only.

[41 FR 6903, Feb. 13, 1976, as amended at 45 FR 3750, Jan. 18, 1980; 45 FR 7484, Feb. 1, 1980; 47 FR 41107, Sept. 17, 1982; 47 FR 51109, Nov. 12, 1982; 48 FR 34470, July 29, 1983; 62 FR 62259, Nov. 21, 1997]

EFFECTIVE DATE NOTE: At 62 FR 62259, Nov. 21, 1997, § 809.10 was amended in paragraph (a) by adding at the end of the first sentence ''or as provided in paragraph (e) of this section'' and by adding new paragraph (e), effective Nov. 23, 1998.

Subpart C—Requirements for Manufacturers and Producers

§ 809.20 General requirements for manufacturers and producers of in vitro diagnostic products.

(a) [Reserved]

(b) *Compliance with good manufacturing practices.* In vitro diagnostic products shall be manufactured in accordance with the good manufacturing practices requirements found in part 820 of this chapter.

[41 FR 6903, Feb. 13, 1976, as amended at 42 FR 42530, Aug. 23, 1977; 43 FR 31527, July 21, 1978]

§ 809.30 Restrictions on the sale, distribution and use of analyte specific reagents.

(a) Analyte specific reagents (ASR's) (§ 864.4020 of this chapter) are restricted devices under section 520(e) of the Federal Food, Drugs, and Cosmetic Act (the act) subject to the restrictions set forth in this section.

(b) ASR's may only be sold to:

(1) In vitro diagnostic manufacturers;

(2) Clinical laboratories regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), as qualified to perform high complexity testing under 42 CFR part 493 or clinical laboratories regulated under VHA Directive 1106 (available from Department of Veterans Affairs, Veterans Health Administration, Washington, DC 20420); and

(3) Organizations that use the reagents to make tests for purposes other than providing diagnostic information to patients and practitioners, e.g., forensic, academic, research, and other nonclinical laboratories.

(c) ASR's must be labeled in accordance with § 809.10(e).

(d) Advertising and promotional materials for ASR's:

(1) Shall include the identity and purity (including source and method of acquisition) of the analyte specific reagent and the identity of the analyte;

(2) Shall include the statement for class I exempt ASR's: ''Analyte Specific Reagent. Analytical and performance characteristics are not established'';

(3) Shall include the statement for class II or III ASR's: ''Analyte Specific

Reagent. Except as a component of the approved/cleared test (name of approved/cleared test), analytical and performance characteristics are not established''; and

(4) Shall not make any statement regarding analytical or clinical performance.

(e) The laboratory that develops an in-house test using the ASR shall inform the ordering person of the test result by appending to the test report the statement: ''This test was developed and its performance characteristics determined by (Laboratory Name). It has not been cleared or approved by the U.S. Food and Drug Administration.'' This statement would not be applicable or required when test results are generated using the test that was cleared or approved in conjunction with review of the class II or III ASR.

(f) Ordering in-house tests that are developed using analyte specific reagents is limited under section 520(e) of the act to physicians and other persons authorized by applicable State law to order such tests.

(g) The restrictions in paragraphs (c) through (f) of this section do not apply when reagents that otherwise meet the analyte specific reagent definition are sold to:

(1) In vitro diagnostic manufacturers; or

(2) Organizations that use the reagents to make tests for purposes other than providing diagnostic information to patients and practitioners, e.g., forensic, academic, research, and other nonclinical laboratories.

[62 FR 62259, Nov. 21, 1997]

EFFECTIVE DATE NOTE: At 62 FR 62259, Nov. 21, 1997, §809.30 was added to subpart C, effective Nov. 23, 1998.

PART 810—MEDICAL DEVICE RECALL AUTHORITY

Subpart A—General Provisions

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AUTHORITY: 21 U.S.C. 321, 331, 332, 333, 334, 351, 352, 360h, 371, 374, 375.

SOURCE: 61 FR 59018, Nov. 20, 1996, unless otherwise noted.

Subpart A—General Provisions

§810.1 Scope.

Part 810 describes the procedures that the Food and Drug Administration will follow in exercising its medical device recall authority under section 518(e) of the Federal Food, Drug, and Cosmetic Act.

§810.2 Definitions.

As used in this part:

(a) *Act* means the Federal Food, Drug, and Cosmetic Act.

(b) *Agency* or *FDA* means the Food and Drug Administration.

(c) *Cease distribution and notification strategy* or *mandatory recall strategy* means a planned, specific course of action to be taken by the person named in a cease distribution and notification order or in a mandatory recall order, which addresses the extent of the notification or recall, the need for public warnings, and the extent of effectiveness checks to be conducted.

(d) *Consignee* means any person or firm that has received, purchased, or used a device that is subject to a cease distribution and notification order or a mandatory recall order. Consignee does not mean lay individuals or patients, i.e., nonhealth professionals.

(e) *Correction* means repair, modification, adjustment, relabeling, destruction, or inspection (including patient